

Agilent Ref: 10010016-1
United States Application Serial No. 09/772,723

REMARKS

In view of the following remarks, the Examiner is requested to withdraw the rejections and allow Claims 1-14 and 45-54, the only claims pending and currently under examination in this application.

Formal Matters

Claims 1-14 and 45-54 were examined and rejected.

Claims 15-44 were previously cancelled.

Claim 54 has been amended to correct a typographical error.

As the above amendments enter no new matter to the application, their entry by the Examiner is respectfully requested.

Rejection under 35 U.S.C. § 112, First Paragraph

In the Office Action, Claims 1-14 and 45-54 were rejected under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement for a number of different asserted issues.

In traversing this rejection, each of the issues raised by the Examiner is addressed separately below:

(A) Providing Step

The Examiner asserts that there is lack of adequate written description for the providing step of the claims. In making this assertion, the Examiner states:

(1)The "providing" step in instant Claims 1 and 8 can be interpreted several ways. While there is written support for a customer providing multiple vessels to the central fabrication facility (page 10, lines 18-22), there does not appear to be adequate written support in the claims, specification, and/or drawings as originally filed, for the broadest interpretation of this step which includes other parties performing the providing, such as the central fabrication station location providing the plurality of individual vessels.

As reviewed by the MPEP, the written description requirement is satisfied if

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the patent specification describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

According to MPEP§ 2163.02:

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art, that as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

With respect to the providing step, Claims 1 and 8 do not require the identity of who provides the starting material—only that the plurality of vessels be provided. With respect to the embodiment of the specification in which the customer provides the plurality to the central fabricator, this embodiment is merely representative the different embodiments of the invention. One of ordinary skill in the art would understand that the plurality of individual vessels is provided by someone, such as a customer and if not, by someone at the fabrication station or anyone else who wishes to fabricate an array of biopolymers because the array cannot be fabricated without the starting materials. As such, one of skill in the art, reading the specification, would know that any party may provide the plurality, including the central fabricator, and still come within the invention that was in the possession of the Applicant.

(B) Corresponding Support

The Examiner asserts that there is lack of adequate written support for the phrase "using the map identifier to identify vessels corresponding to regions of the array." In making this assertion, the Examiner states:

(2) While this section of page 17 (last paragraph) mentions an identifier on the array and using the identifier and map identifier to obtain the corresponding identity map for the array, it does not provide written support for "using the map identifier to identify vessels corresponding to regions of the array," as stated in new Claim 53.

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The Applicant submits that one of ordinary skill in the art would recognize that the specification clearly supports "using the map identifier to identify vessels corresponding to regions of the array." For example, at P. 10, lines 14-17, the specification teaches that a customer should be provided "with a map of the identity of the vessels to the corresponding regions of the substrate onto which the biopolymers from respective vessels are deposited to form the array." Additional support is further provided at P. 11, lines 2-5; and Table 1 of the specification. One of skill in the art, from reading the disclosure, would fully realize that the phrase "using the map identifier to identify vessels corresponding to regions of the array" is adequately supported in the specification. Accordingly, this rejection may be withdrawn.

(C) Unique identifier that is not composition information

The Examiner asserts that there is lack of adequate written support for the limitation of Claim 54 which recites "wherein each of said vessels is marked with a unique identifier that is not composition information from that vessel." In making this assertion, the Examiner states:

3) Applicants point to support on p. 18 (lines 5-7) for the limitation of claim 54 reciting "wherein each of said vessels is marked with a unique identifier that is not composition information from that vessel." This section of page 18 (lines 5-7) does not mention anything about marking vessels or that the identifier with no composition information.

Throughout the disclosure, the Applicant describes the unique identifier as specifically marking an individual vessel from the plurality of vessels provided. This allows the identity of the vessels to be mapped to the corresponding regions of the substrate, to which it was deposited. As evident from the examples provided in the specification at P. 10, lines 17-22 and Table 1, it is clear that the unique identifier is an identifying mark with respect to the specific location of that specific vessel, i.e., "tray number, column number, row number." Furthermore, in describing the processor at the user station, the specification teaches that "once processor has obtained the identity map it can obtain additional array layout information, such as the sequence identity of each polynucleotide in each well and hence the sequence identity of polynucleotides at array features. Additional array layout information such

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as the polynucleotide sequences might be stored locally by the customer..." at P. 18, lines 5-10. Accordingly, the specification clearly teaches that the polynucleotide sequences of each vessel are a completely separate entity from the identity map and therefore, the unique identifier of the claims is not composition information from that vessel. As such, there is full support for the limitation that the vessel is marked with an identifier that is not composition information. Accordingly, this rejection may be withdrawn.

D. New Matter Rejection

The Examiner asserts that Claims 53 and 54 are considered to be new matter. In making this assertion, the Examiner states:

4) Because there is a lack of written basis for the full scope of the providing step for amended Claims 1 and 8, the phrase "wherein each of said vessels is marked with a unique identifier that is not composition information from that vessel" as stated in new Claim 53, and the phrase "wherein each of said vessels is marked with a unique identifier that is not composition information from that vessel" as stated in new Claim 54, are considered new matter.

As set forth above with respect to points A-C, the written description requirement is adequately satisfied with respect to the questioned phrases above. Accordingly, Claims 53 and 54 do not represent new matter, contrary to the Examiner's assertion.

The Applicant respectfully submits that the rejection under 35 U.S.C. § 112, First Paragraph has been sufficiently addressed and respectfully requests withdrawal of this rejection.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1-14 and 45-54 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. This rejection is respectfully traversed.

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The MPEP teaches that the requirements of 35 U.S.C. §112 are met if the claims of an application, when read in light of the specification, reasonably apprise one of skill in the art of what is being claimed.¹ In view of the foregoing discussion, the Applicant submits that the clarity requirements of 35 U.S.C. §112, second paragraph, have been met, and this rejection may be withdrawn.

Claims 1 and 8

In the Office Action, the Examiner alleges that Claims 1 and 8 recite the phrase "providing a plurality" which is vague and indefinite.

In response, it is submitted that the phrase "providing a plurality" specifies that the distinct biopolymer starting materials are contained in a plurality of source vessels from which the biopolymers will be deposited onto the substrate during array fabrication. In particular, Figure 4 demonstrates "providing a plurality" of vessels, wherein the biopolymers from each of the plurality of vessels get deposited onto the same array. The three different trays (360, 364, and 368) are each "provided" that contain a "plurality" of vessels. Each "vessel" i.e., each well on each tray, contains a biopolymer that will be deposited onto the array during fabrication. As such, one of skill in the art when reading the specification knows the metes and bounds of the phrase "providing a plurality" in Claims 1 and 8. Therefore, this rejection may be withdrawn.

The Examiner further alleges that Claims 1 and 8 recite the phrase "each member" which is vague and indefinite.

The Applicant contends that one of skill in the art would completely understand the meaning of "each member" from the disclosure. The specification discloses that each vessel in the form of wells (for example, in a 96-well format) has "an Identifier for example in the format of 'tray number, column number, row number.'" One of skill in the art, from reading the disclosure, would fully understand that "each member" of the plurality refers to each vessel of the plurality of vessels

¹ MPEP § 2173.05(a): "If the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the statute (35 U.S.C. 112 second paragraph) demands no more."

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provided. For example, in a 96-well plate, each vessel is equivalent to each well. As such, a 96-well plate has 96 individual vessels and "each member" refers to each individual vessel. Accordingly, one of skill in the art would know that "each member" refers to each vessel from reading the disclosure. Therefore, the phrase "each member" is not vague and indefinite and this rejection may be withdrawn.

Claim 53

The Examiner further asserts that Claim 53 recites the phrase "corresponding to" which is vague and indefinite.

In response, the Applicant submits that one of skill in the art would understand the meaning of "corresponding to regions of the array" as described in the specification. It is well known that array fabrication typically involves depositing previously obtained biopolymers at predetermined locations on a substrate. Accordingly, the phrase "corresponding to regions of the array" simply teaches that each original source vessel, which contains a specific biopolymer has a "corresponding" region on the fabricated array in which the same specific biopolymer has been deposited. Furthermore, the present invention discloses a map that allows one to identify the specific vessel and its corresponding regions on the array. One of skill in the art would know the typical methods of array fabrication and would fully understand the meaning of "corresponding to regions of the array" as disclosed in the specification. Moreover, one of skill in the art would know to use the map identifier to identify the original source vessels that correspond to regions of the array from the instant specification. Accordingly, this rejection may be withdrawn.

Claim 54

In the Office Action, the Examiner asserts that Claim 54 contains steps (a) through (e) separated by semicolons which is vague and indefinite. It is believed that the above amendment to Claim 54 addresses this issue.

In view of the above remarks, this rejection may be withdrawn.

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Rejection under 35 U.S.C. § 103

In the Office Action, Claims 1-14 and Claims 45-54 continue to be rejected under 35 U.S.C. § 103(a) as being obvious over Hunkapiller in view of Zeleny, Brown, Anderson, Shakib and Balaban.

With respect to rejections made under 35 U.S.C. § 103, MPEP § 2142 states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. **Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). [emphasis added]

For the reasons set forth below, there is no teaching or suggestion in the combination of cited references of all of the elements of the claimed invention. Specifically, there is no teaching or suggestion of the element of the claims that requires one to assign each member of a plurality of source vessels a unique format identifier and then save in a memory a map of the unique format identifiers assigned to each original source vessel.

The present claims are directed to a method of fabricating an addressable array of biopolymers. Independent Claims 1, 8, and 54 clearly specify that each member of a plurality of source vessels is assigned/or marked with a unique format identifier and that a map of the unique format identifiers assigned to each original source vessel is saved in a memory.

Claim 1 is representative and reads as follows:

Claim 1

A method of generating an addressable array of biopolymers on a substrate, comprising:

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- (a) providing a plurality of individual vessels each containing a biopolymer wherein said plurality is provided in a defined format;
- (b) assigning a unique format identifier to each member of said plurality;
- (c) obtaining the biopolymers from the plurality of individual identified vessels;
- (d) depositing the biopolymers onto different regions of the substrate so as to fabricate the array;
- (e) saving in a memory a map of the identity of the vessels to the corresponding regions of the substrate onto which the biopolymers from respective vessels are deposited, in association with a map identifier, wherein said map of the identity of the vessels comprises a unique format identifier of each vessel of said plurality;
- (f) applying the map identifier to the substrate or a housing carrying the substrate;
- (g) shipping the fabricated array with applied map identifier to a remote location.

As such, the claims clearly provide that each member of a plurality of source vessels is assigned a unique format identifier and that a map of the identity of the vessels is the collection of unique format identifiers assigned to each vessel in the plurality.

In maintaining this rejection, the Examiner asserts that the claims may be interpreted with a broader meaning of the phrase "unique format identifier" and that "each member" can be interpreted to be each vessel or each biopolymer.

However, as set forth below and in the prior responses, the Applicant's unique identifier is the unique format identifier assigned to the original vessel prior to fabrication of the array and cannot be interpreted to also include the biopolymer itself. The Applicant's claimed format identifier is assigned to the original vessel prior to fabrication of the array and not to the biopolymer of the vessel. The claimed identity map is the collection of unique format identifiers assigned to each vessel in the plurality.

For example, a customer wishing to fabricate an array may provide one 96-well plate and one 48-well plate, with each wells containing a specific biopolymer. The customer may request that half of the 96-well plate and all of the 48-well plate be deposited onto the array. As such, 48 biopolymers from plate 1 and 48 biopolymers from plate 2 will be deposited onto the array. According to the present invention, each well (member) within the 96-well and 48-well plate will be assigned a

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unique format identifier, such as (tray number, column number, row number) so that an identity map can be generated. The identity map provides the identity of the original source vessels with the corresponding regions of the substrate as clearly evident from the example provided in Table 1 of the specification.

TABLE 1

Vessel Identifier (tray, column, row)	Feature Identifier (column, row) with reference to upper left hand corner
1A1	A1
1A2	A2
1A3	A3
1C1	1C1
1C2	1C2

It is clear that the phrase "unique format identifier" means an identifier with respect to the specific vessel, i.e., "tray number, column number, row number" and not the biopolymer in the vessel.

Moreover, when describing the processor at the user station, the disclosure teaches that "once processor has obtained the identity map it can obtain additional array layout information, such as the sequence identity of each polynucleotide in each well and hence the sequence identity of polynucleotides at array features. Additional array layout information such as the polynucleotide sequences might be stored locally by the customer..." at P. 18, lines 5-10.

Therefore, it is clear that the polynucleotide sequences of each vessel are a completely separate entity from the identity map of format identifiers. Therefore, the claimed unique identifier is not composition information from that vessel.

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Since the words of a claim must be read in light of the teachings of the specification, the unique format identifier does not include the identity of the biopolymer itself. Instead, the language of the claims clearly limits the format identifier to the original source vessels and not the biopolymer.

In maintaining the rejection, the Examiner continues to rely on Zeleny to provide the elements of assigning a unique identifier to each member of a plurality of individual vessels and saving in a memory a map of the identity of the vessels made up of a collection of unique identifiers. According to the Office Action, Zeleny teaches a map of the individual identity of substances with regions on an array. Furthermore, the Examiner alleges that Figure 2 of Zeleny shows unique format identifiers for each member wherein member is interpreted to be the substance.

As such, the Examiner's rejection hinges on the interpretation that "format identifier" can include information about the biopolymer itself. However, as demonstrated above, such an interpretation is not supported by the specification or the words of the claims.

The Applicant submits that the language of the claims clearly specifies that the unique format identifier is assigned to each member of the vessel and accordingly, cannot be given the broader meaning to further include the biopolymer.

As such, Zeleny, in combination with the other cited references, fails to disclose the elements of assigning each member of a plurality of source vessels a unique format identifier and saving in a memory a map of the unique format identifiers assigned to each original source vessel.

Because the cited combination of references fails to teach the elements of the claimed invention in which each member of a plurality of source vessels is assigned a unique format identifier and saving in a memory a map of the unique format identifiers assigned to each original source vessel, it is respectfully submitted that Claims 1-14 and Claims 45-52 are not obvious under 35 U.S.C. § 103(a) over Hunkapiller in view of Zeleny, Brown, Anderson, Shakib and Balaban and that this

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rejection may therefore be withdrawn.

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CONCLUSION

The Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone Dianne Rees at (650) 485-5999.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078.

Respectfully submitted,

Date: September 13, 2005

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